APR 1 2 2006

510(k) Summary

In accordance with the requirements of 21 CFR 807.92, Smith & Nephew is hereby submitting a 510(k) Summary for the VersaJet™ Hydrosurgery System.

510(k) # K060782

1. Submitter:

   Smith & Nephew, Inc.
   Wound Management
   11775 Starkey Road
   Largo, FL 33773

   Company Contact:

   Terry C. McMahon
   Regulatory Affairs Manager-Devices
   727-399-3785 Telephone
   727-399-3468 Fax

2. Device Name:

   Trade name: VersaJet™ Hydrosurgery System

   Common name: Pulse lavage with sharp debridement

   Classification Name: Jet Lavage, 21 CFR 880.5475

   Product Classification: II

   Code: FQH

3. Identification of Legally Marketed Device:

   Hydrocision Debridement System (VersaJet)
   Smith & Nephew, Inc.
   Largo, Florida
   510(k) # K011612

4. Device Description:

   The VersaJet Hydrosurgery System uses pressurized streams of sterile fluid to cut, ablate and remove tissue and foreign matter from wounds and to resect and remove material in a variety of surgical applications. The device provides cutting, irrigation and evacuation in the same tool.

The stream of fluid simultaneously washes the tissue surface and removes foreign material from the wound or surgical site. The stream of saline simultaneously washes the tissue surface and vacuums away foreign material, including contamination and infected and necrotic tissue from the wound. The fluid acts to ablate the surface of the tissue and propel excised tissue and debris out of the surgical site. The debris and fluid are directed immediately within the instrument into a flexible tube, which carries the effluent to the drain or a collection canister.

The system employs two basic system components: the reusable power console unit and the sterile, disposable pump cartridge, handpiece and tubing assembly.

5. Intended Use:

The VersaJet Hydrosurgery System is intended for wound debridement (acute and chronic wounds, burns), soft tissue debridement, and cleansing of the surgical site in applications in which, in the physicians judgment, require sharp debridement and pulsed lavage irrigation.

6. Comparison of Technological Characteristics

There have been no changes to the design of the predicate VersaJet Hydrosurgery System cleared in 510(k) number K011612 and the device in this premarket notification. This submission supports an expansion of the indications for use of the device to include debridement of burn wounds.

7. Clinical Literature Review

Rennekampff et al evaluated seventeen patients with burn wound areas of between 0.5% and 5% total body surface (TBSA) involving the face, arm, hand, leg and foot. VersaJet™ was able to sufficiently debride superficial partial thickness and mid-dermal partial thickness wounds for subsequent placement of Biobrane® (Bertek Pharmaceuticals Inc, NC, USA), with successful autografting of deeper partial thickness wounds following excision. In a sub-group of seven of the patients, bacterial analysis of the wound bed was also performed pre- and post-debridement. Of the four wounds exhibiting pre-debridement bacterial load, two showed no growth post-debridement and one showed a reduction in bacterial load from $>10^5$ colony-forming units down to only one colony. Of the three wounds with no pre-debridement growth, one showed bacterial growth post-debridement. No post-operative infections or complications were reported. The authors concluded that VersaJet™ may lower the bacterial load in burn wounds and is effective in its ability to debride irregular and complex contours and sparing vital tissue.

Klein et al described their experience of 21 burn patients debrided from January 2003 onwards. This series was later extended and a total of 44 patients (age range 3 months – 83 years) were reported by Klein et al[13]. In this cohort, VersaJet™ was used routinely in the excision of eschar from the eyelids, fingers and web spaces as well as being utilized for a variety of other areas such as the scalp, ears, lip and periareola. VersaJet™ was used as an adjunct to Watson and Gouilian knives or electrocautery, depending on the depth of the remainder of the burn wound. While the learning curve, inefficient excision of large surfaces and costs associated with the device were noted, no patients required repeat grafting as the result of inadequate excision with VersaJet, and no patients had graft loss as the result of excessive tissue excision. The authors concluded that VersaJet™ is a useful adjunct in burn wound excision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2006

Smith & Nephew, Inc.
c/o Mr. Terry C. McMahon
Regulatory Affairs Manager - Devices
11775 Starkey Road
Largo, Florida 33773

Re: K060782
Trade/Device Name: VersaJet™ Hydrosurgery System
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet lavage
Regulatory Class: II
Product Code: FQH
Dated: March 21, 2006
Received: March 22, 2006

Dear Mr. McMahon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

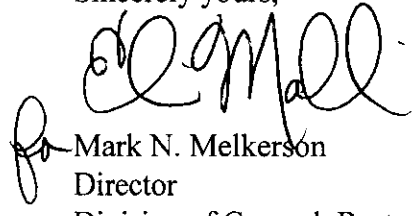
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060782

Indications for Use

510(k) Number (if known): K060782

Device Name: VersaJet™ Hydrosurgery System

Indications for Use:

The VersaJet Hydrosurgery System is intended for wound debridement (acute and chronic wounds, burns), soft tissue debridement, and cleansing of the surgical site in applications in which, in the physicians judgment, require sharp debridement and pulsed lavage irrigation.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060782